EvySaif
Research Solutions

CDSCO Import License Document Checklist

Form MD-14 application for the MD-15 import license, Medical Devices Rules, 2017

Prerequisite before filing MD-14

The Indian applicant holds a wholesale license, a manufacturing license, or the registration certificate in Form MD-42.

Application and fees

- [ ] Covering letter
- [ ] Application in Form MD-14 on the CDSCO medical device online portal
- [ ] Fee challan per the Second Schedule: per manufacturing site plus per distinct device

Applicant and authority documents

- [ ] Power of attorney per Part I, Fourth Schedule, authenticated by First Class Magistrate, Indian Embassy in the country of origin, or apostille
- [ ] Wholesale license, manufacturing license, or MD-42 registration certificate of the applicant
- [ ] Constitution details of the applicant

Regulatory certificates and quality system

- [ ] Free Sale Certificate or marketing authorization from the country of origin regulator, duly notarized
- [ ] Overseas regulatory approvals held for the device
- [ ] ISO 13485 certificate for the manufacturing site, with supporting QMS documentation

Technical documentation

- [ ] Device Master File in the MDR 2017 structure
- [ ] Plant Master File in the MDR 2017 structure
- [ ] Clinical evaluation and clinical evidence for safety and performance
- [ ] For software and AI devices: software documentation per the CDSCO guidance (2026)

Labeling

- [ ] Device labels compliant with Chapter VI of MDR 2017 and Legal Metrology requirements
- [ ] Instructions for use

Special situations

- [ ] No predicate in India: market permission in Form MD-27 obtained before the import license
- [ ] Demonstration or evaluation units needed before grant: test license via Form MD-16 to MD-17

Government fees (Second Schedule, verify at filing)

Class A: USD 1,000 per site + USD 50 per device Class B: USD 2,000 per site + USD 1,000 per device
Class C and D: USD 3,000 per site + USD 1,500 per device Statutory review window: nine months

Full guide: evysaif.com/blog/cdsco-import-license-md-14-md-15/

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